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5/25/98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53273

May 19, 1998

Marcelino R. Amaral, Jr.
Marcelino Amaral and Sons Dairy
20207 4th Avenue
Stevinson, California 95374

WARNING LETTER

Dear Mr. Amaral:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on May 4 and 5, 1998, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon has revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On March 10, 1998, you consigned a cull dairy cow (identified by USDA laboratory report number 208341) to be slaughtered as human food. This cow, which was delivered for introduction into interstate commerce by your firm, was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this animal revealed the presence of sulfadimethoxine in the liver at 2.00 parts per million (ppm), and in the muscle at 0.49 ppm. A tolerance level for sulfadimethoxine has been established for the edible tissue of lactating dairy cattle at 0.10 ppm.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

4. You lack an adequate inventory system for determining the quantities of drugs used to medicate your cows and calves.

You are adulterating the drug Albon brand sulfadimethoxine boluses within the meaning of Section 501(a)(5) of the Act when you do not use this drug in conformance with prescribed labeling. The labeling requires a seven-day withdrawal period prior to slaughter for food use. Failure to adhere to the prescribed withdrawal time is likely the cause of the presence of violative levels of sulfadimethoxine in the tissues of the animal you sold for food use. Failure to comply with the label instructions on the drugs you use presents the likely possibility that illegal residues will occur again and makes the drugs unsafe to use.

We request that you take prompt action to ensure that dairy cows and calves which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated animal into interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated animal to be slaughtered into food for human consumption where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

Your firm has established a history of offering cull dairy cows and calves for sale for human food use which have been found to be adulterated with drug residues. According to USDA analytical reports, during the period of November 25, 1992, through March 10, 1998, your

firm sold four cows which contained violative levels of penicillin or sulfadimethoxine. During this same period, you also sold three calves which were found CAST positive by USDA analysis due to the possible presence of violative levels of antibiotics. As a result of the violative residues, an inspection was conducted of your dairy on October 24, 25 and 28, 1996. During this inspection you were warned that it is illegal to market cull dairy cattle which contain illegal levels of antibiotics. A Warning Letter, dated December 13, 1996, was issued to you as a result of this inspection. Also, the U.S. Department of Agriculture has sent you letters for cull cows and calves in which analysis found violative levels of drug residues. You have failed to take adequate corrective action. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrective action may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen (15) days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, Investigator, Food and Drug Administration, P.O. Box 169, Fresno, California 93707.

Sincerely yours,

Charles D Moas
Acting District Director

for Patricia C. Ziobro
District Director
San Francisco District

cc: Santokh S. Takhar, DVM
Hilmar Animal Hospital
P.O. Box 399
Hilmar, California 95324